5 Year Summary of FDA Medical Device 483s 2015-2019



Jeanne Moldenhauer

www.pda.org/bookstore

5 Year Summary of FDA Medical Device 483s

Jeanne Moldenhauer

PDA
Bethesda, MD, USA
DHI Publishing, LLC
River Grove, IL, USA

10 9 8 7 6 5 4 3 2 1

ISBN: 978-1-942911-45-6

Copyright © 2020 Jeanne Moldenhauer

All rights reserved.

All rights reserved. This book is protected by copyright. No part of it may be reproduced, stored in a retrieval system or transmitted in any means, electronic, mechanical, photocopying, recording, or otherwise, without written permission from the publisher. Printed in the United States of America.

Where a product trademark, registration mark, or other protected mark is made in the text, ownership of the mark remains with the lawful owner of the mark. No claim, intentional or otherwise, is made by reference to any such marks in the book. Websites cited are current at the time of publication. The author has made every effort to provide accurate citations. If there are any omissions, please contact the publisher.

While every effort has been made by the publisher and the author to ensure the accuracy of the information expressed in this book, the organization accepts no responsibility for errors or omissions. The views expressed in this book are those of the author and may not represent those of either Davis Healthcare International or the PDA, its officers, or directors.



Connecting People, Science and Regulation®



PDA Global Headquarters

Bethesda Towers, Suite 150 4350 East-West Highway Bethesda, MD 20814 United States www.pda.org/bookstore 001-301-986-0293 Davis Healthcare International Publishing, LLC

2636 West Street River Grove IL 60171 United States www.DHIBooks.com

CONTENTS

I	Introduction				
	What is included in a FDA 483?	- 1			
	How Does a FDA 483 Compare to a Warning Letter?	- 1			
	Responding to a FDA 483	2			
	During the Inspection	2			
	The Actual Company Response to the FDA Regarding the FDA 483	2			
	Following the Response	3			
	Why Review FDA 483s?	3			
	Literature Cited	4			
2	Summary of Medical Device FDA Observations	5			
	Background	5			
	Five Year Data Summaries can be found on the following pages:				
	21 CFR 803.11	6			
	21 CFR 803.17	6			
	21 CFR 803.18	6			
	21 CFR 803.30	7 7			
	21 CFR 803.32				
	21 CFR 803.40	7			
	21 CFR 803.50	7			
	21 CFR 803.52	7			
	21 CFR 803.53	8			
	21 CFR 803.56	8			
	21 CFR 806.10	8			
	21 CFR 806.20	8			
	21 CFR 807.20	8			
	21 CFR 807.21	8			
	21 CFR 807.25	8			
	21 CFR 807	9			
	21 CFR 809.10	9			
	21 CFR 812.2	9			

Table of Contents

21 (CFR	812.5	9
21 (CFR	812.7	9
21 (CFR	812.18	9
21 (CFR	812.25	9
21 (CFR	812.05	9
21 (CFR	812.40	9
21 (CFR	812.42	9
21 (CFR	812.43	9
21 (CFR	812.46	10
21 (CFR	812.66	10
21 (CFR	812.100	10
		812.110	11
21 (CFR	812.140	11
21 (CFR	812.150	12
21 (CFR	820.20	13
21 (CFR	820.22	13
		820.25	14
		820.30	14
	_	820.40	15
		820.50	16
		820.60	17
		820.65	17
		820.70	17
		820.72	18
		820.75	18
		820.80	19
		820.86	19
		820.90	19
	_	820.100	20
		820.120	20
		820.130	20
		820.140	21
		820.150	21
		820.160 820.170	21 21
	_	820.170	21
		820.181	21
		820.184	21
		820.186	21
		820.198	22
	_	820.200	22
		820.250	22
		821.25	22
		821.30	23
		821.50	23
		860.7	23
Z1 (000.7	۷3

	Table of Contents		
	Literature Cited	23	
3	Analysis of Medical Device FDA 483 Summary	24	
	Background	24	
	What are the Most Frequently Occurring Observations?	25	
	Conclusion	26	
	Literature Cited	27	
4	Available Resources	28	
	About the Author	30	